

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

STEVEN HOUSER,	:	
Plaintiff,	:	
	:	
v.	:	CIVIL ACTION NO. 21-0676
	:	
ARTHUR FELDMAN AND TEMPLE	:	
UNIVERSITY,	:	
Defendants.	:	

MEMORANDUM OPINION

This case concerns, *inter alia*, an investigation by Defendant Temple University (“Temple”) into alleged research misconduct by Plaintiff Steven Houser. Houser has filed a Motion for a Protective Order to either enjoin the investigation or subject it to the discovery rules of the Federal Rules of Civil Procedure.

Temple’s investigation was prompted by complaints received by the Department of Health and Human Services’ Division of Investigative Oversight, Office of Research Integrity (“ORI”) through the scientific research website “PubPeer.” These complaints alleged that Houser had engaged in possible research misconduct in 15 different papers that were supported by National Institute of Health grants (“PubPeer Papers”). In September 2020, in response to the PubPeer complaints, the ORI sent a letter to Temple requesting that it, in accordance with 42 C.F.R § 93.307, “examine all of the issues to determine whether each of the allegations have merit and are credible” and advising further that “the allegations require a prompt and thorough assessment to determine whether further action is necessary.” ORI’s letter then described the process Temple must follow in undertaking its assessment of the allegations against Houser. For example, Temple is required to “take all reasonable and practical steps to obtain custody of all of the research records and evidence needed to conduct the research misconduct proceeding, . . .

inventory the records and evidence, and sequester them in a secure manner.” Further, it is to “pursue diligently all significant issues and leads discovered that are determined relevant to the inquiry. . . .”

In accordance with the letter, Temple commenced the investigation into the 15 papers (“PubPeer Inquiry”). It notified Houser of the PubPeer Inquiry by email on September 25, 2020. A few months later, in January 2021, Temple instructed Houser to preserve and provide it with documents relating to the PubPeer Papers and informed him that there would be an initial discussion of the specific allegations against him once Temple reviewed the documents he provided. Houser retained counsel, provided detail on his role in nine of the challenged papers and requested that Temple clarify the scope and nature of its inquiry. Shortly thereafter, Houser filed this lawsuit.

Six months later, in the midst of the discovery period in this litigation, Temple informed Houser of what it referred to as a “mandatory site-visit” scheduled as part of the PubPeer Inquiry at which Houser was expected to appear and be prepared to provide copies of research records and discuss research spaces used and individuals involved with the PubPeer Papers. Houser then filed the present Motion to “safeguard [his] rights” and to enjoin Temple from “engaging in sweeping extra-judicial discovery” as part of its PubPeer Inquiry. Temple counters that the PubPeer Inquiry is federally directed and mandated by the ORI and that Plaintiff, through his Motion, is seeking to impede the investigation.

The ORI was established by the Public Health Services Act (the “Act”) as an independent entity tasked with investigating misconduct in biomedical and behavioral research supported by federal funds. 42 U.S.C. § 289b(e). The Act devises a larger regulatory framework governing investigations of research misconduct supported by federal funds. In relevant part, the Act

directs the Secretary of Health and Human Services (the “Secretary”): to promulgate regulations: (1) defining research misconduct, § 289b(a)(3)(A); (2) requiring institutions which receive federal funds for research have an administrative process to review reports of research misconduct conducted at, or sponsored by, the institution, § 289b(b)(1); and, (3) creating a process for ORI to receive allegations and reports of research misconduct, carry out investigations and take necessary remedial action, § 289b(c). The Secretary responded to this statutory mandate by “promulgating an elaborate regulatory mosaic,” which created an intricate three-tier process by which institutions and the ORI would jointly assess allegations of research misconduct. *Anversa v. Partners Healthcare Sys., Inc.*, 835 F.3d 167, 170 (1st Cir. 2016); 42 C.F.R. Part 93. Within this regulatory mosaic, “research misconduct” is defined as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” 42 C.F.R. § 93.103. A finding of research misconduct requires a showing, by a preponderance of the evidence, of “a significant departure from accepted practice of the relevant research community” that was “committed intentionally, knowingly, or recklessly.” 42 C.F.R. § 93.104.

Allegations of research misconduct allegations are first reviewed at the funded institution through a two-step process. The first phase is known as an “inquiry,” which is “warranted” if, among other reasons, the allegation falls within the regulatory definition of research misconduct. 42 C.F.R. § 93.307(b). The inquiry requires an “initial review of the evidence”, which includes all research records, interviews and other necessary evidence, to determine whether the allegation warrants an investigation. 42 C.F.R. § 93.307(b)-(d). The inquiry culminates in a written report, which the researcher who is the subject of the inquiry can review and comment on. 42 C.F.R. § 93.307(f). While the institution generally “must complete the inquiry within 60

calendar days of its initiation,” the regulations provide lenience for additional time where circumstances “clearly warrant” the extension. 42 C.F.R. § 93.307(g). The institution must document the reasons for any delays in completing the inquiry in the report. *Id.*

If the inquiry finds that there is a “reasonable basis for concluding” that there has been research misconduct involving federal funds, 42 C.F.R. § 93.307(d)(1), and that particularized allegations of research misconduct “may have substance,” 42 C.F.R. § 93.307(d)(2), then the institution must notify both the researcher facing the inquiry and the ORI of the inquiry results within 30 days and provide a copy of the inquiry report. 42 C.F.R. § 93.309(a). After such a finding, the institution is obligated to conduct a “thorough and sufficiently documented investigation” within 120 days, absent an extension from the ORI. 42 C.F.R. §§ 93.310, 93.311(a)-(b). The institution must give the researcher notice of the allegations that the investigation will explore. 42 C.F.R. § 93.310(c). As with the inquiry, the investigation culminates in a written report which the researcher is once again afforded the opportunity to review and comment on. 42 C.F.R. §§ 93.312(a), 93.313(g). Regardless of whether the investigation concludes that research misconduct occurred, the report, its findings and conclusions, all relevant evidence, and any information about actions taken or pending by the institution must be forwarded to the ORI. 42 C.F.R. § 93.315. Once the ORI receives the investigation report and the accompanying materials, it conducts its own assessment of the allegations and can take appropriate administrative action. 42 C.F.R. § 93.407(a). The researcher can appeal and contest any of the ORI’s findings to an administrative law judge, the Assistant Secretary for Health in HHS, and a federal court under the Administrative Procedure Act. 93 C.F.R. §§ 93.500(b), 93.523(b). In short, the PubPeer Inquiry is part of an administrative investigation that Temple is required to conduct under the rubric of the Public

Health Services Act.

The Supreme Court has been clear that courts are not to impede an administrative investigation. Indeed, an administrative agency, like the ORI, is entitled to broad deference in investigating possible violations of law because it:

has a power of inquisition . . . which is not derived from the judicial function. It is more analogous to the Grand Jury, which . . . can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not. When investigative and accusatory duties are delegated by statute to an administrative body, it, too, may take steps to inform itself as to whether there is a probable violation of the law.

United States v. Morton Salt Co., 338 U.S. 632, 652 (1950). The Court has further instructed that investigations should not be stopped “at the threshold of inquiry” because doing so “would render substantially impossible [the] effective discharge of the duties of investigation and enforcement which Congress has placed upon [the agency].” *Okla. Press Pub. Co. v. Walling*, 327 U.S. 186, 213 (1946); *Univ. of Med. and Dentistry of N.J. v. Corrigan*, 347 F.3d 57 (3d Cir. 2003) (“It is beyond cavil that the very backbone of an administrative agency’s effectiveness in carrying out the congressionally mandated duties of industry regulation is the rapid exercise of the power to investigate the activities of the entities over which it has jurisdiction. . . .” (internal citation omitted)). Bearing these principles in mind, courts should exercise utmost caution when asked to interfere with investigative powers delegated to agencies like the ORI. *See, e.g.*, *E.E.O.C. v. Kronos, Inc.*, 694 F.3d 351, 369-70 (3d Cir. 2012) (overturning a protective order which “effectively impede[d] the EEOC’s ability to pursue any leads. . . .”). Judicial proceedings are only appropriate after the investigation has concluded because, “[j]udicial supervision of agency decisions to investigate might hopelessly entangle the courts in areas that would prove to be unmanageable and would certainly throw great amounts of sand into the gears of the administrative process.” *Corrigan*, 347 F.3d at 64.

Here, the statutory and regulatory scheme demand that Temple work with the ORI to complete its assessment of the misconduct allegations, which is at the inquiry phase. Indeed, given the statutory scheme and the jurisdictional concerns of a federal court weighing in on an investigation conducted by an administrative agency, it does not behoove this Court to enjoin the investigation or require that it be conducted pursuant to the Federal Rules of Civil Procedure. *See e.g., Medici v. Lifespan Corp.*, 384 F. Supp. 3d 218 (D. Mass 2019) (holding that there was no federal jurisdiction over an institution's investigation into research misconduct); *Anversa*, 855 F.3d at 178-180 (staying litigation until resolution of ORI administrative proceedings). Houser's motion for a protective order shall therefore be denied.

An appropriate order follows.

BY THE COURT:

/s/ Wendy Beetlestone, J.

WENDY BEETLESTONE, J.